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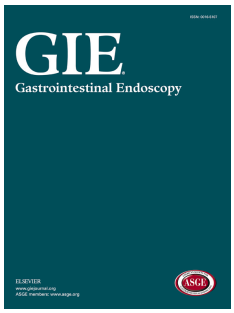

COVID-19 pandemic and personal protective equipment shortage: protective efficacy comparing masks and scientific methods for respirator reuse

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Abstract

Background and Aims
The abrupt outbreak of COVID-19 and its rapid spread over many health care systems in the world led to personal protective equipment (PPE) shortening, which cannot be faced only by the reduction in their consumption nor by the expensive and time-requiring implementation of their production. It is thus necessary to promote PPE rational use, highlighting possible differences in terms of efficacy among them and promoting an effective technique to reuse them.

Methods
A literature search was performed on PubMed, Scopus, Cochrane database, and Google Scholar and from 25 top cited papers, 15 were selected for relevance and impact.

Results
Most studies on prior respiratory virus epidemic to date suggest surgical masks not to be inferior compared with N95 respirators in terms of protective efficacy among health care workers. The use of N95 respirators should be then limited in favor of high-risk situations. Concerning respirators reuse, highly energetic short-wave ultraviolet germicidal irradiation (UVGI) at 254 nm was proficiently applied to determine N95 respirators decontamination from viral respiratory agents, but it requires careful consideration of the type of respirator and of the biological target.

Conclusions
Rational use and successful reuse of respirators can help facing PPE shortening during a pandemic. Further evidences testing UVGI and other decontamination techniques are an unmet need. The definitive answer to pandemic issues can be found in artificial intelligence and deep learning: these groundbreaking modalities could help in identifying high-risk patients and in suggesting appropriate types and use of PPE.

Introduction

The SARS-CoV-2 outbreak abruptly resulted in COVID-19 pandemic, leading almost to the collapse of many health care systems in the world, overwhelmed with potentially infectious patients seeking testing and care. In the attempt to prevent the spread of a viral infection to and from health care workers, the health community generally relies on the efficacy of personal

protective equipment (PPE): gloves, masks, respirators, goggles, face shields, and gowns. PPE, once omnipresent and easily available in the hospital environment, are now scarce and precious. This situation driven not only by the number of COVID-19 cases but also by misinformation, panic buying, and stockpiling during a pandemic is of tremendous concern especially for the health community that is at greatest risk for exposure. Digestive endoscopists are between those at highest risk to get infected because of aerosolization during the procedures. The reduction in the consumption of PPE through the postponement of the elective and non-urgent outpatient clinical practice does not sufficiently compensate for the scarcity of these goods. Moreover, an increase in the production of PPE would require a time interval that many health systems cannot afford given the speed of the spread of the infection.

Among the various types of PPE, surgical masks, N95 respirators, and powered air-purifying respirators (PAPRs) are the currently mostly used. Surgical masks (**Figure 1**) are usually loose-fitting and disposable; they create a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment and they vary by quality and levels of protection. N95 respirators (**Figure 2**) have the advantages of blocking at least 95% of aerosol (<5 µm) and droplet-size (5 µm to 50 µm) particles; their use requires an initial and periodic fit testing and it is associated with poor tolerance by users due to breathing resistance and heat. N95 respirators correspond to European filtering face piece (FFP) 2 standard (**Figure 3**), which have at least a 94% filter capacity. PAPRs (**Figure 4**) are battery-powered blowers that provide positive airflow through a filter. The type of filter is dictated by the amount of airborne contaminant exposure; they provide head and neck protection and they do not require fit testing, especially if they do not have a tight-fitting face piece, but they are usually associated with increased perception of eye dryness and they are by far the most expensive PPE against respiratory infections.

Facing the PPE shortage, it is necessary to underline possible differences in terms of efficacy in preventing the viral transmission among the currently mostly used PPE in order to facilitate their rational use. PPE scarcity could be furthermore mitigated through the identification of an effective reuse technique. The primary aim of this review is therefore to summarize the protective efficacy of masks and respirators in preventing the spread of respiratory infections and to propose a proper biological decontamination process to take into consideration respirators reuse.

Methods

A literature search was on PubMed, Scopus, Cochrane database and Google Scholar using terms “Surgical Masks,” “Masks,” “N95 respirators,” “Powered Air-Purifying Respirators,”

"Respirators," "Respiratory Viruses," "Respirators/PPE reuse," "Respirators/PPE disinfection," and "Health Care Workers." From 25 top-cited articles, 15 were selected for relevance and impact.

Results

Protective efficacy of health care workers comparing masks

According to a Cochrane approved systematic review on physical interventions to prevent respiratory virus transmission conducted in 2011, surgical masks and N95 respirators are the most consistent and comprehensive supportive measures adopted among health care workers. The highest quality cluster-Randomized Controlled Trials (RCTs) included in this systematic review proved that N95 respirators are noninferior to surgical masks in terms of efficacy in preventing viral transmission.[1]

What is reported by this review is in accordance with a classic, highly cited case-control study carried out in Hong Kong during Severe Acute Respiratory Syndrome (SARS) in 2003 evaluating personal protective practices (handwashing, wearing paper masks, surgical masks or N95 respirators, gloves and gowns): a multivariate logistic regression conducted to analyze the impact of each protective measure demonstrated that N95 respirators and surgical masks have similar protective effect.[2]

The equivalence in terms of efficacy between the 2 types of PPE considered was similarly demonstrated in the specific case of influenza. A quantitative assessment of the efficacy of surgical masks and N95 respirators to filter influenza virus in patients with acute influenza infection carried out in 2009 demonstrated that N95 respirators and surgical masks were equally able to prevent the spread of reverse transcription-polymerase chain reaction (RT-PCR)–detectable virus when worn correctly by 9 patients with laboratory-confirmed acute influenza.[3] In the same way, an accurate RCT realized in 2009 comparing the efficacy of surgical masks versus N95 respirators among ER nurses during influenza demonstrated the equal efficacy between the 2 practices (absolute risk difference, −0.73%; 95% CI, −8.8% to 7.3%; $P > .05$).[4] The latest RCT available focusing on influenza prevention among 2371 randomized health care workers published in September 2019 confirms that surgical masks and N95 respirators do not imply significant differences in terms of laboratory-confirmed influenza infection prevention (difference 1.0%; 95% CI, −0.5% to 2.5%; $P > .05$).[5]

A systematic review and meta-analysis of observational studies and RCTs published in 2017 confirmed both PPE to be effective in protecting against SARS (OR, 0.13; 95% CI, 0.03–0.62 and OR, 0.12; 95% CI, 0.06–0.26 for surgical masks and N95 respirators, respectively).

Correspondingly to previous evidences, N95 respirators did not confer superior protection against viral infections or influenza-like illness compared with surgical masks, but they were demonstrated for the first time to be more effective in protecting from general clinical respiratory illness (RR, 0.47; 95% CI, 0.36–0.62) and laboratory-confirmed bacterial illness (RR, 0.46; 95% CI, 0.34–0.62).[6]

Similar evidences derived from the most recent version of a systematic review and meta-analysis updated in February 2020. Among a total of 6 RCTs involving 9171 participants no statistically significant differences in preventing laboratory-confirmed influenza (RR, 1.09; 95% CI, 0.92-1.28; *P* > .05), laboratory-confirmed respiratory viral infections (RR, 0.89; 95% CI, 0.70-1.11), laboratory-confirmed respiratory infection (RR, 0.74; 95% CI, 0.42-1.29) and influenza-like illness (RR, 0.61; 95% CI, 0.33-1.14) were reported using surgical masks or N95 respirators. N95 respirators proved to have a protective effect against laboratory-confirmed bacterial colonization (RR, 0.58; 95% CI, 0.43-0.78).[7,8]

The use of PAPRs was mainly proposed during the outbreak of ebola[9] and, bearing in mind that their greater level of respiratory protection than N95 masks has not been subjected to rigorous scientific investigation, it is generally recommended in situations in which a live airborne virus is being handled.[10]

Scientific methods for respirators reuse

Disposable filtering facepiece respirators are not approved for routine decontamination and reuse as standard of care, but a possible strategy to face PPE shortage during specific emergency situations is to reuse them following a proper biological decontamination process to render infectious material inactive. It is very important that the treatment does not deteriorate the respirators material decreasing its filtering power against respiratory infectious species or releases any toxic residues on the respirators surface. PPE reuse can be realized exclusively by the original health care worker.

The Centers for Disease Control and Prevention (CDC) report that decontamination methods such as autoclave, 160°C dry heat, 70% isopropyl alcohol, and soap and water cause significant respirators filter degradation, which consequently allows excessive particle penetration levels.[11]

An observational study conducted in 2009 during an influenza pandemic compared several ways of decontamination on N95 respirators: ultraviolet germicidal irradiation (UVGI), ethylene oxide (EtO), vaporized hydrogen peroxide (VHP), microwave oven irradiation, and bleach.[12] These decontaminating processes were evaluated for changes in N95 respirators

physical appearance, odor, and laboratory performance (filter aerosol penetration and filter airflow resistance); however, this study did not assess the efficiency of the decontamination methods to inactivate viable microorganisms. The microwave oven irradiation and bleach decontamination methods were determined to be the least desirable among the 5 methods tested, due to excessive degradation of the respirators surface and to unpleasant odor respectively. UVGI, EtO, and VHP were found to be the most promising decontamination methods as concerns respiratory viral agent elimination and respirators integrity maintenance; however, concerns were remarked about the throughput capabilities for EtO and VHP.

Three decontamination methods against H5N1 influenza virus were similarly compared in another observational study carried out in 2011: UVGI, microwave-generated steam and moist heat were compared when used to purify N95 respirators from viral contamination. A highly energetic short-wave UVGI at 254 nm was demonstrated to be the most effective method in quantitatively reducing RT-PCR viral RNA on N95 respirators suffices.[13]

An experimental study conducted in 2015 confirmed 254 nm UVGI to be efficient in decontaminating N95 respirators from viral respiratory agents; the authors evaluated the effect of ultraviolet germicidal irradiation not only in terms of filtration performance, but also in terms of structural integrity. UVGI exposition was performed in conditions of controlled humidity and temperature, in custom-made chamber (91 cm × 31 cm × 64 cm high) fitted with two 15-watt T-150 254 nm UV-C lamps and lined with black felt to minimize reflections. It was proved that UVGI did not substantially affect the filtration performance nor the flow resistance at doses up to 950 J/cm². Reduction in structural integrity was reported only for higher doses of UVGI exposition.[14]

Supplementary evidences derive from another experimental study performed in 2018, which testified UVGI efficiency on influenza-contaminated N95 respirators.[15] N95 respirators samples contaminated with H1N1 influenza were treated for approximately 60 to 70 seconds with approximate UVGI irradiance of 17 mW/cm² for a total of dose of ~1 J/cm²; all contaminated and treated surfaces were cut out and virus was extracted; viable influenza was quantified using a median tissue culture infectious dose assay. Significant reductions (≥3 log) in influenza viability were observed on the respirators' surfaces.

Discussion

Most studies on prior respiratory virus epidemic to date suggest similar efficacy of surgical masks to N95 respirators. A strong protective effect of both masks has been in fact demonstrated, especially when used in combination with other protective measures of hand washing, eye protection, gowns, and gloves. International organizations, first and foremost the

World Health Organization, do, however, recommend health care workers to use N95 respirators in high-risk situations such as aerosol generating procedures. In specific emergency situations such as COVID-19 endemic, the use of N95 respirators should be then restricted among general public and nonhigh-risk medical staff, in favor of high-risk health care workers. The use of PAPRs should be limited to high-risk health care personnel dealing with airborne virus outbreaks. In order to avoid the excessive waste of PPE, the same respirator can be worn while caring for multiple patients who have the same diagnosis without removing it; respirators maintain their protection when used for extended periods. However, using one respirator for longer than 4 hours can lead to discomfort and should be avoided.[16]

As far as it concerns respirators reuse, overall, UVGI is widely known as effective and useful decontaminative technique. Its virucidal mechanism was proficiently applied to determine N95 respirators decontamination from viral respiratory agents. The highly energetic short-wave UVGI at 254 nm was demonstrated to be especially effective in reducing RT-PCR influenza RNA but there are some critical points that need attention: insufficient UVGI dose exposition cannot reach all the internal surfaces of respirators and, consequently, it can leave active infectious material; on the other hand, excessive UVGI dose can partially affect the structural integrity of respirators and lower their filtration performance. Furthermore, each PPE can tolerate a maximum number of disinfection cycles depending on its design and type of components; valves, for instance, technically cannot be sterilized with UVGI.

Conclusions and Perspectives

In the midst of the COVID-19 pandemic, it is essential to avoid excessive consumption of PPE and to implement their rational use. As long as surgical masks and N95 respirators demonstrated to be equally efficient in protecting health care workers from respiratory viral infection, N95 respirators should be preferably intended for high-risk situations. A further possible strategy to face PPE shortage is to reuse them following a proper biological decontamination process. The UVGI method proved to be a valid alternative to decontaminate N95 respirators, but it requires careful consideration of the type of respirator and of the biological target. Further evidences testing this technique on different models are an unmet need. The definitive answer to these problems could be found in artificial intelligence and deep learning: these groundbreaking modalities are in rapid worldwide growth and their application in a pandemic could help in identifying high-risk patients and situations, in suggesting appropriate use and types of PPE and in saving lives. Humanity is exposed to a pandemic almost every 10 years, but to date it appears that, even if it was already predicted, the problem of PPE shortage and their inappropriate use has not been dammed yet. Victims of this are first and

foremost healthcare workers. The time has come for the historical lesson of previous pandemics to be learned.

Disclosures

Professor Guido Costamagna is consultant for Cook Medical, Boston Scientific and Olympus. Dr Ivo Boškoski is consultant for Apollo Endosurgery, Cook Medical, Boston Scientific and Endo Tools, and is Apollo Endosurgery Research Grant Holder. Professor Michael B. Wallace and Dr Camilla Gallo have nothing to disclose.

Figures legend

Figure 1. Surgical mask
Figure 2. N95 respirator
Figure 3. Filtering face piece (FFP) 2 standard
Figure 4. Powered air-purifying respirators (Dräger X-plore 8000, ©Drägerwerk AG & Co. KgaA, Lübeck, Germany).

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Journal CME Conflict of Interest: Disclosure and Attestation

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Boston Scientific	Research grant	
Olympus	Research grant	
Ninepoint Medical	Research grant	
Cosmo/Aries Pharmaceuticals	Research grant	
Virgo Inc	Stock Options	
GI Supply (2018)	Consulting on behalf of Mayo Clinic	
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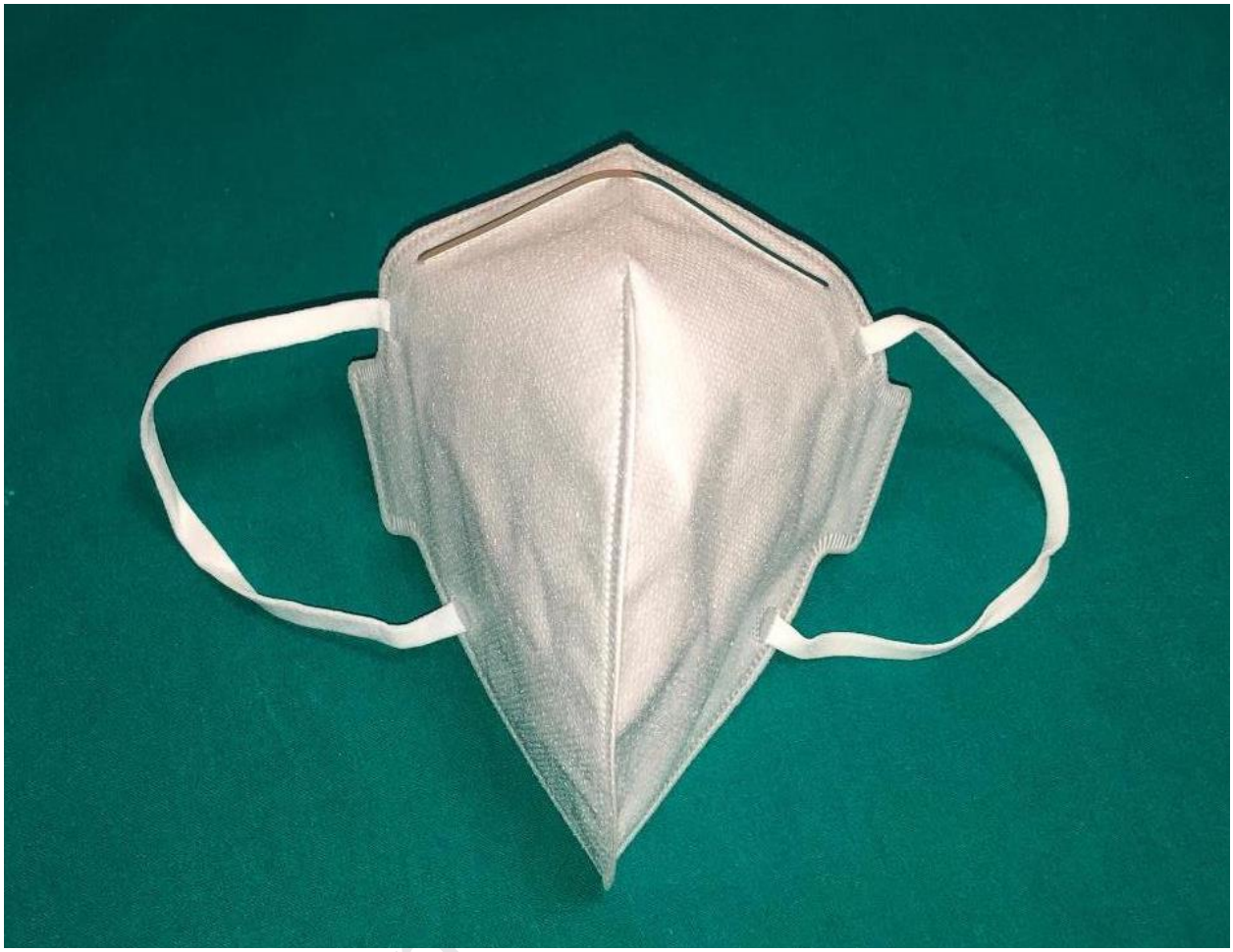


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Abbreviations:

PPE: personal protective equipment

UVGI: ultraviolet germicidal irradiation

FFP: filtering face piece

PAPRs: powered air-purifying respirators

RCT: cluster-Randomized Controlled Trials

SARS: Severe Acute Respiratory Syndrome

RT-PCR: Reverse Transcription-Polymerase Chain Reaction

CDC: Centers for Disease Control and Prevention

EtO: ethylene oxide

VPH: vaporized hydrogen peroxide